Financial Conflict of Interest

- In August 2012, the U.S. Public Health Service (PHS) of the U.S. Department of Health and Human Services, which includes NIH, began to enforce new regulations on financial conflicts of interest (FCOI) to protect the objectivity of sponsored research.

- All individuals listed on a PHS-funded protocol or grant, regardless of title or position, who may be responsible for design, conduct, or reporting of research must complete a disclosure form in order to disclose all financial interests that would reasonably appear to be related to their institutional responsibilities.
Subrecipient Compliance

• PHS’ FCOI rules require the following:
  – Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee institution or the subrecipient will apply to subrecipient investigator, and include time periods to meet disclosure requirements, if applicable, and FCOI reporting requirements.
  – A subrecipient institution that relies on its own FCOI policy must report identified FCOIs to the awardee institution (Duke) in sufficient time to allow the awardee Institution to report the FCOI to the PHS awarding component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.
Disclosure Deadlines

• At time of Application: Each investigator must have completed a disclosure form

• Update: Submit an updated disclosure form within 30 days of discovering or acquiring (e.g., through purchase, trade, marriage or inheritance) a new reportable financial interest

• Anniversary: At least annually throughout the time you participate on the grant
Significant Financial Interest (SFI) Includes:

- Anything of monetary value that meets any of the following criteria (when combined for you, your spouse or partner and/or your dependent children);
- Income >$5,000 (U.S. dollars) over the past 12 months, including salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship, royalties);
- As of the date of disclosure, any combination of income and equity in a publicly traded company >$5,000 (U.S. dollars) (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Any equity interest in a non-publicly traded company, i.e. a privately owned company (equity is any stock, stock option, or other ownership interest, whether or not the value can be determined through reference to public prices or other reasonable measures of fair market value);
- Income >$5,000 (U.S. dollars) for intellectual property rights (e.g. royalties, licensing fees, etc.)

SFI does NOT include:

- Financial interests or activities that do not relate to your academic or professional work at your employer organization;
- Salary support received through your organization or salary support through your organization’s administered sponsored awards;
- Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not directly control the investment decisions made in these vehicles;
- Income from seminars, lectures and teaching engagements sponsored by U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education;
- Income from service on advisory committees or review panels for U.S. Federal, state or local government agencies; U.S. Institutions of higher education or U.S. research institutes; U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.
Examples of a FCOI

- Owning shares in a privately held outside entity and your grant is designed to advance that entity’s interests
- Cherry picking the best data from your research to bolster the value of licensed intellectual property
- Making sure that procurement decisions favor a company that you also own
Investigators are required to disclose certain information about all sponsored or reimbursed travel, if the investigator and the travel both meet certain criteria (next slide).

If the travel qualifies for reporting (i.e., is sponsored and is related to professional responsibilities) using the Duke Travel web site you must report:

• The identity of the sponsor/organizer (if the sponsor is a company that is working through an intermediary (e.g., a marketing company), report the primary sponsor of the trip rather than the intermediary;
• The purpose of the trip (speaking, consulting, meetings, etc.);
• The destination of the trip; and
• The duration of the travel, specifically the date you left and the date you returned.
SPONSORED TRAVEL FAQS

You are NOT required to disclose travel expenses if you are NOT responsible for the design, conduct or reporting of research funded by the Public Health Service (PHS) or other agencies/sponsors that have adopted the PHS regulations (including NIH).

You MUST disclose third party paid travel related to your institutional responsibilities if you ARE responsible for the design, conduct or reporting of research funded by the PHS (or other agencies/sponsors that have adopted the PHS regulations):

**Third party paid travel means:**
- Third party directly pays in whole or in part for travel on your behalf;
- You pay for travel and third party reimburses you in whole or in part;
- Your institution pays in whole or in part for travel and the third party reimburses your institution.

**PHS regulations require you to disclose travel paid by:**
- External professional organizations and societies, academic journals and publishing companies; and
- ANY travel reimbursed or sponsored by a foreign institution of higher education or the government of another country.

**PHS regulations exclude travel paid by:**
- Your institution or funded by a sponsored award to your institution;
- U.S. Federal, state or local government agencies;
- U.S. Institutions of higher education or U.S. research institutes; and
- U.S. academic teaching hospitals or U.S. medical centers that are affiliated with U.S. Institutions of higher education.
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<th>TRAVEL TIPS</th>
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<tr>
<td>Travel paid for by industry (directly paid to the individual, not through your own institution)</td>
<td>Yes</td>
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<td>Travel paid for by a non-profit foundation</td>
<td>Yes</td>
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<td>Travel paid for by a professional society (e.g. American Cancer Society, European Society for Pediatric Infectious Diseases)</td>
<td>Yes</td>
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<td>Travel to a university paid for by the university to give a lecture</td>
<td>No</td>
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<td>Travel to a board meeting in another state paid for by the American Heart Association</td>
<td>Yes</td>
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<td>Travel to an advisory board meeting for a nonprofit for which you are reimbursed</td>
<td>Yes</td>
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<td>Travel paid for by the American Cancer Society to an academic meeting to present NIH grant-funded research</td>
<td>Yes</td>
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<td>Travel to another university to give a seminar where the university reimburses you, but the university received funding for the seminar from a pharmaceutical company</td>
<td>No, if the reimbursement came from university</td>
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<td>Travel that combines a trip to an advisory board paid for by the company and a family vacation for which I am paying for myself</td>
<td>The vacation part of the trip must be paid for by personal funds and not by the company that is paying for the business trip. (only need to disclose the duration of the business portion of the trip)</td>
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Organizations That Are Part of the U.S. PHS

• U.S. Public Health Service includes the following components
  – National Institutes of Health (NIH)
  – Centers for Disease Control and Prevention (CDC)
  – Food and Drug Administration (FDA)
  – Substance Abuse and Mental Health Services Administration (SAMHSA)
  – Office of the Assistant Secretary for Preparedness and Response (ASPR)
  – Office of Global Affairs (OGA)
  – Agency for Toxic Substances and Disease Registry (ATSDR)
  – Health Resources and Services Administration (HRSA)
  – Indian Health Service (IHS)
  – Agency for Healthcare Research and Quality (AHRQ)
  – Office of the Assistant Secretary for Health